due be charged to Deposit Account Number 50-0877 with reference to (RDID 0006 US).

Respectfully submitted,
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(Date)

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CLEAN VERSION OF REPLACEMENT CLAIMS FOR ENTRY DURING PROSECUTION OF US APPLICATION N0. 09/711,855

1. System for the extrapolation of a glucose concentration, comprising:

a data input device for entering insulin doses administered (I_i) and their times of administration (t_i),

the same or a second data input device for entering carbohydrates (KH_j)

consumed or to be consumed, and their times of consumption (t_j),

a unit for determining the actual glucose concentration (G_a) in a patient's bodily fluid at a specific point in time (t_a),

a memory unit for storing administered insulin doses and their times of administration, and carbohydrates consumed and their times of consumption,

an evaluation device for evaluating the data stored in the memory unit and extrapolating a glucose concentration at a point in time (t_p), whereby t_p is after t_a, and the extrapolation comprises the following steps:

determination of the portion (I_{wirk}) of insulin doses that take effect within the interval between t_a and t_p,

determination of the portion (KH_{wirk}) of carbohydrates consumed that take effect in the interval between t_a and t_p,

determination of an extrapolated glucose concentration G_p at the point in time tp with consideration for I_{wirk} and KH_{wirk}.

2. System according to Claim 1, in which the glucose concentration G_p is determined at the point in time using the following formula:

$G_p = G_a - I_{wirk} * D * SE + KH_{wirk} * E + X$,

whereby D is an empirical weighting factor, SE is the patient's insulin sensitivity, E is a factor, and X=0 or is unequal to zero.

3. System according to Claim 2, in which $E = R_{KH} * F$, whereby R_{KH} is the carbohydrate reduction factor and F is an empirical factor.

4. System according to Claim 2, in which X, as the addent, contains the quantity $GB = I_{basal} * SE * C$ or is equal to GB, whereby I_{basal} is the patient's basal insulin demand over 24 hours, SE is the patient's insulin sensitivity, and C is an empirical weighting factor.

5. System according to Claim 2, in which X, as the addend, contains the quantity SG * A, whereby SG is the slope of the glucose concentration at the point in time t_a, and A is an empirical weighting factor.

6. System according to Claim 1, in which the unit used to determine the actual glucose concentration G_a is a microdialysis device.

7. System according to Claim 1 that also includes a display unit for displaying the extrapolated glucose concentration G_p.

8. System according to Claim 1 that also includes a warning unit that emits a warning signal when the extrapolated glucose concentration G_P is outside a selected normal range.

9. System according to Claim 1 in which the user enters the carbohydrate units consumed (KH_j).

10. System according to Claim 1 in which the system contains a control unit for an insulin infusion device or is connected to such a device, and in which the insulin doses administered (I_i) and their times of administration (t_i) are transmitted from the control unit to the date input device for entering insulin doses.

12. System according to Claim 1 in which the quantity of carbohydrates consumed (KH_{wirk}) that takes effect in the period between t_a and t_p is calculated using the following formula

$$KH_{WIRK} = \sum_{j=1}^{m} \int_{t_a}^{t_p} C_{KH}(t)dt * KH_j$$

whereby C_{KH} represents the quantity of carbohydrates that are bioavailable at the point in time t and therefore represents the carbohydrate flooding profile, with

$$\int_0^{\infty} C_{KH}(t)dt = 1.$$

32. System according to Claim 4, in which X, as the addend, contains the quantity SG * A, whereby SG is the slope of the glucose concentration at the point in time ta, and A is an empirical weighting factor.

33. System according to claim 1 in which the portion of insulin doses (I_{wirk}) that take effect in the period between t_a and t_p is calculated using the following formula

$$I_{WIRK} = \sum_{i=1}^{n} \int_{t_a}^{t_p} C_I(t)dt * I_i;\ n = \text{number of insulin doses to be considered}$$

whereby CI represents the quantity of insulin that is bioavailable at the point in time t and therefore represents the insulin effectiveness profile; with

$$\int_0^\infty C_I(t)dt = 1.$$

34. System according to claim 2 in which the portion of insulin doses (I_{wirk}) that take effect in the period between t_a and t_p is calculated using the following formula

$$I_{WIRK} = \sum_{i=1}^{n} \int_{t_a}^{t_p} C_I(t)dt * I_i;\ n = \text{number of insulin doses to be considered}$$

whereby CI represents the quantity of insulin that is bioavailable at the point in time t and therefore represents the insulin effectiveness profile; with

$$\int_0^\infty C_I(t)dt = 1.$$

35. System according to Claim 2 in which the quantity of carbohydrates consumed (KH_{wirk}) that takes effect in the period between t_a and t_p is calculated using the following formula

$$KH_{WIRK} = \sum_{j=1}^{m} \int_{t_a}^{t_p} C_{KH}(t)dt * KH_j$$

whereby C_{KH} represents the quantity of carbohydrates that are bioavailable at the point in time t and therefore represents the carbohydrate flooding profile, with

$$\int_0^\infty C_{KH}(t)dt = 1.$$

36. System according to Claim 1, in which the point in time t_p is from 0.5 to 5 hours after t_a.

37. System according to Claim 1, in which the point in time t_p is at least 2 hours after t_a and up to 4 hours after t_a.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

[13. System for determination of insulin doses to be administered comprising:

a data input device for entering insulin doses administered to the patient (Ii) and their times of administration (t_i),

a device for determining the actual glucose concentration (G_a) in a patient's bodily fluid at a specific point in time (t_a),

a memory unit for storing the doses of insulin administered and their times of administration,

an evaluation device for evaluating the data stored in the memory unit, and determination of an insulin dose to be administered subcutaneously, or a carbohydrate intake whereby the evaluation comprises the following steps:

determination of the portion (I_{wirk}) of insulin doses that are consumed within the period between t_a and t_p,

determination of the insulin doses to be administered, with consideration for I_{wirk}.]

[14. System according to Claim 13, in which the point in time t_p is from 0.5 to 5 hours after t_a.]

[15. System according to Claim 13, in which the point in time t_p is at least 2 hours after t_a and up to 4 hours after t_a.]

[16. System according to Claim 13, in which a glucose concentration G_p is measured at point in time t_p and this glucose concentration is used to calculate the insulin dose to be administered.]

[17. System according to claim 16, in which the glucose concentration G_p at the point in time t_p is calculated using the following formula:

$G_p = G_a - I_{wirk} * D * SE + X$,

whereby D is an empirical weighting factor, SE is the patient's insulin sensitivity, and X=0 or is unequal to zero.]

[18. System according to Claim 13 that includes a data input device (EK) for entering carbohydrate units consumed by a patient and their times of consumption, and then determines the portion (KH_{wirk}) of carbohydrate units consumed that take effect in the interval between t_a and t_p and takes KH_{wirk} into account in the determination of the insulin dose to be administered.]

[19. System according to Claim 18, in which the glucose concentration G_p is calculated at the point in time t_p using the following formula:

$G_p = G_a + KH_{wirk} * E - I_{wirk} * SE * D + X$,

whereby E and D are empirical weighting factors, SE is the patient's insulin sensitivity, and X=0 or is unequal to zero.]

[20. System according to Claim 17 , in which X, as the addend, contains the quantity $G_{basal} = I_{basal} * SE * C$, whereby I_{basal} is the patient's basal insulin demand over a 24-hour period, SE is the patient's insulin sensitivity, and C is an empirical weighting factor.]

[21. System according to Claim 17 in which X, as the addend, contains the quantity SG * A, whereby SG is the slope of glucose concentration at the point in time t_a, and A is an empirical weighting factor.]

[22. System according to Claim 16, in which the insulin dosage ID to be administered subcutaneously is calculated using the following formula:

$ID = ((G_P - G_R) / SE * E) + Y$, whereby

G_R is a target glucose concentration or a maximum acceptable glucose concentration, E is an empirical weighting factor, and Y = 0 or is unequal to zero.]

[23. System according to Claim 22, whereby $Y = R_{KH} * KH_{REST} / SE * F$ is or contains this value as the addend, whereby RKH is the patient's carbohydrate reduction factor, KH_{REST} is the quantity of carbohydrates resorbed between the actual point in time (t_a) and the end of the period in which the insulin is effective, and F is an empirical weighting factor.]

[24. System according to Claim 3, in which the quantity of insulin to be administered is calculated in intervals of from 1 to 30 minutes.]

[25. System according to Claim 13 that contains a display unit for displaying the insulin dose to be administered.]

[26. System according to Claim 13 that also contains a microdialysis device with a microdialysis catheter.]

[27. System according to Claim 13 that has an administration unit for administering a calculated insulin dose.]

[28. System according to Claim 13 in which the administration unit is integrated in the microdialysis catheter.]

[29. System according to Claim 13 that contains a query unit that performs a query to determine if a certain insulin dose should be administered and with which the user releases the administration of insulin.]

[30. System according to Claim 13 that contains a warning unit that emits a warning signal when an extrapolated glucose concentration Gp leaves a normal range or when an insulin dose to be administered exceeds a predefined quantity.]

[31. System according to Claim 13 that contains a display unit for displaying an insulin dose to be administered, as well as an editing unit which the patient can use to change the insulin dose to be administered before it is administered.]

[38. System according to claim 14, that includes a data input device (EK) for entering carbohydrate units consumed by a patient and their times of consumption, and then determines the portion (KH_{wirk}) of carbohydrate units consumed that take effect in the interval between t_a and t_p and takes KH_{wirk} into account in the determination of the insulin dose to be administered.]

[39. System according to claim 15, that includes a data input device (EK) for entering carbohydrate units consumed by a patient and their times of consumption, and then determines the portion (KH_{wirk}) of carbohydrate units consumed that take effect in the interval between t_a and t_p and takes KH_{wirk} into account in the determination of the insulin dose to be administered.]

[40. System according to claim 16, that includes a data input device (EK) for entering carbohydrate units consumed by a patient and their times of consumption, and then determines the portion (KH_{wirk}) of carbohydrate units consumed that take effect in the interval between t_a and t_p and takes KH_{wirk} into account in the determination of the insulin dose to be administered.]

[41. System according to claim 17, that includes a data input device (EK) for entering carbohydrate units consumed by a patient and their times of consumption, and then determines the portion (KH_{wirk}) of carbohydrate units consumed that take effect in the interval between t_a and t_p and takes KH_{wirk} into account in the determination of the insulin dose to be administered.]

[42. System according to Claim 19, in which X, as the addend, contains the quantity $G_{basal} = I_{basal} * SE * C$, whereby I_{basal} is the patient's basal insulin demand over a 24-hour period, SE is the patient's insulin sensitivity, and C is an empirical weighting factor.]

[43. System according to Claim 20 in which X, as the addend, contains the quantity SG * A, whereby SG is the slope of glucose concentration at the point in time t_a, and A is an empirical weighting factor.]

[44. System according to Claim 17, in which the insulin dosage ID to be administered subcutaneously is calculated using the following formula:

$ID = ((G_P - G_R) / SE * E) + Y$, whereby

G_R is a target glucose concentration or a maximum acceptable glucose concentration, E is an empirical weighting factor, and $Y = 0$ or is unequal to zero.]

[45. System according to Claim 27 that contains a display unit for displaying an insulin dose to be administered, as well as an editing unit which the patient can use to change the insulin dose to be administered before it is administered.]